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| 09/836,348 | 04/18/2001 | William A. Koehring | N1239-009 | 8755 |

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EXAMINER

IBRAHIM, MEDINA AHMED

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 07/09/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------------|--|
| Office Action Summary | Application No. 09/836,348 | Applicant(s) KOEHRING, WILLIAM A. | |
| | Examiner Medina A. Ibrahim | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claims 1-33 are pending and are under examination.

Information Disclosure Statement

Initialed and dated copy of Applicant's IDS form 1449, Paper No. 2 is attached to the instant Office action.

Drawings

No drawings have been filed with the instant application.

Objections

The specification is objected to because of the following: The statement of deposit in the specification, page 34, does not comply with the deposit requirement set forth in 37 CFR 1.801-1.809. The deposit statement in the specification must be amended to include the deposit accession number.

Claims 1, 17, and 19 are objected to for failing to recite complete Accession information. The ATCC Accession No. must be filled in as appropriate.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of the 35 U.S.C. 112, 1st paragraph may be satisfied by a deposit of the seed. The specification does not disclose a reproducible method to obtain the exact same seed and it is unclear if the seed is readily available to the public.

The statement on page 34 of the specification indicating Applicants' intention to make an enabling deposit of the claimed invention with the ATCC is noted. However, there is no indication that the seed has been deposited and no indication that the seed is available to the public. A deposit of at least 2500 seeds is required for an enablement purpose.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seed has been deposited under the Budapest Treaty and that the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See 37 C.F.R. 1.808. See 37 CFR 1.809 for additional explanation of these requirements.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

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(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 days or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and,

(e) the deposit will be replaced if it should ever become unviable.

Claims 17-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for producing inbred corn seed RAA1, RAA1-derived or further-derived corn plants. However, the specification does not disclose a repeatable process to reproduce the claimed inbred seed RAA1. Therefore, a person skilled in the art would not be able to practice the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 6-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6 “wherein said plant is male sterile” renders the claim indefinite because the plant of claim 2 is not male sterile.

In claim 8, “A” should be changed to ---The---, and “the” before “cells” be deleted, for proper dependency. Also, “protoplasts of the tissue culture” is inconsistent with claim 7 which recites “tissue culture of regenerable cells”.

In claims 10, 24, and 30 are indefinite in the recitation of “using” and “utilizing” of a composition without any active or positive steps.

In claims 9-10 and 27, after “RAA1”, the ATCC deposit should follow, for clarification

In claim 14, “said corn plant” should be changed to ---said hybrid corn plant---, for proper dependency.

In claim 15, it is unclear how “different” the plants are. Would they be “genetically different”, or otherwise? Dependent claim 16 is included in the rejection.

Claim 17 is indefinite for failing to recite the steps for identifying a plant with decreased vigor, in part (c). Also, ---corn seed---, should be inserted before “RAA1” in line 1, for clarification.

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In claims 19-25, "RAA1-derived corn plant" renders the claims indefinite as it is unclear what is being retained in the derivative or the derived plant.

In claim 21, part (c), ---with--- should be inserted before "another", for clarification.

Claims 19-25, and 29 are indefinite in the recitation of excellent", "early....." "above average.....", "relative maturity", which are relative terms lacking a comparative basis. Also, the metes and bounds of "adapted" are unclear.

In claim 27, ---with--- should be inserted before " a non-transformed " in line 3, for clarification.

In claim 31, "The corn breeding program of claim 30" lacks antecedent basis because claim 30 is drawn to a method rather than a corn breeding program.

Claim 33 is indefinite because "corn endosperm or quality" is not a characteristic. Correction and/or clarification is required.

Written Description

Claims 12-18 and 20-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines.

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Claims 11-16 are drawn to hybrid corn seeds/plants or F1 generation plants produced from crossing two inbred parent corn plants, wherein the identity of only one of the parent plant is known to be RAA1 inbred corn plant, and the other parent plant is unknown.

The specification does not describe all of the F1 generation plants, in terms of their morphological and physiological characteristics. While the specification discloses unique morphological and physiological characteristics of the inbred corn line RAA1, the claims are not limited to those F1 generation plants that retain all of the morphological and physiological characteristics of the inbred corn plant RAA1. Moreover, no genetic markers unique to RAA1 and which are maintained in the progeny plants have been disclosed.

Claims 19-25 and 29-32 are drawn to RAA1-derived corn plants of undisclosed number of generations having unknown identifying characteristics, wherein inbred line RAA1 might be utilized only in the first generation cross. The specification only discloses a single inbred corn line, RAA1 with specified characteristics. These are genus claims. There are insufficient relevant identifying characteristics which would allow one skilled in the art to predictably determine the genomic structure or the phenotypic characteristics of the plant obtained at each level of crossing or at each generation, absent further guidance. The breeding techniques encompass recurrent selection, mass selection, bulk selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation. Each of these breeding techniques would result in a phenotypically different plant. Therefore, substantial variation in morphological and physiological characteristics is expected among the

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species of the claimed genus. The only characteristics disclosed for the plants are the expression of the combination of at least two traits which are described with relative terms that lack comparative basis (see the rejection under 35 USC, 112, 2nd paragraph). Since no identifying characteristics have not been disclosed even for the F1 generation plants, the characteristics of subsequent outcrossed generations have similarly not been described. Therefore, one skilled would not recognize from the disclosure that Applicants are in possession of the invention as broadly claimed.

Claims 26-28 and 33 are drawn to inbred corn plants RAA1 or hybrid corn plants comprising one or more transgenes or single gene conversion that confers specific characteristics and a method. However, since Applicant does not describe the specific chemical or physical characteristics of all transgenes or the phenotypic characteristics of plants transformed therewith, one skilled in the art would not recognize from the specification that Applicants were in possession of the invention as broadly claimed at the time the invention was made.

The Federal Circuit court stated that a written description of an invention “requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material.” *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material”. *Id.* Further, the court held that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and

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that one of skill in the art should be able to “visualize or recognize the identity of members of the genus”. Id.

In the instant case, the disclosure of a single corn inbred line, RAA1, does not provide an adequate written description for the claimed genus, hybrid corn plants/seeds, RAA1-derived or further derived corn plants, wherein only one parent is known or where only one ancestor of the plant is known to be RAA1, and the rest of the ancestors are unknown. Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description Requirement published in Federal Registry/Vol. 66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buendgen (US Patent 5, 866, 763(A), filed Sept. 1996) .

Buendgen teaches an inbred corn line adapted to northern regions of corn belt, designated as ZS01220, plants, plant parts, and progeny thereof, tissue culture methods, hybrid seeds and plants produced by crossing the inbred line ZS01220 with at least one other corn line. The inbred line ZS01220 has an excellent seedling vigor and good pollen shed (table 3A), resistance to stalk lodging, and possesses good tolerance to a number of diseases (see columns 6-14). The reference teaches the inbred includes at least one mutant gene and transgenes that confer important agronomic traits such as insect resistance (column 3, lines 22-35). The claimed hybrid plant/seed differs from the prior art corn/seed, in that it has one parent or at least one ancestor that is RAA1 inbred corn plant. The methods used to produce the claimed plants involve several crosses of the RAA1 parent with non-RAA1 corn plants. However, it is unclear if all of RAA1-specific traits are retained after multiple generations of backcrossing to the non-RAA1 parent plants. There are insufficient specific characteristics that distinguish the claimed corn plants/seeds from the prior art corn plant/seeds. Applicants should note that because the limitations set forth in claims lack comparative basis as set forth in the 112, 2nd paragraph rejection above, these limitations are interpreted by the Office to be identical to those taught by Buendgen. Therefore, the claimed invention is anticipated by or, in the alternative, is obvious over the prior art.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product- by- process claim may be properly rejected over prior art teaching the same product produced by a

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different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare Applicant's plants with those of the prior art, the burden of proof is upon the Applicant to show an obvious distinction between the claimed plants and the plants of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1997).

No claim is allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

June 27, 2002

mai



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